AUG - 6 2003

CardioQ

CARDIAC OUTPUT AND FLUID STATUS MONITORING SYSTEM

Appendix 2A

510(k) SUMMARY

(1) Submitter's information

Name:	Deltex Medical Limited
Address:	Terminus Road
	Chichester
	West Sussex
	PO19 8TX
	U.K.
	Official Correspondent: Lawrence Brookfield - Quality Assurance & Regulatory Affairs Manager
Telephone:	011 44 1243 523174
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Date prepared: May 29, 2003

(2) Device Identification

Proprietary name:	CardioQ
Common/usual name:	Cardiac Output and Fluid Status Monitoring System
Classification name:	Cardiovascular blood flow-meter

(3) Identification of predicate devices

The CardioQ is substantially equivalent to the following previously cleared devices:

Deltex Medical *Esophageal Doppler Cardiac Function Monitor* - 510(k) No. K951369

Arrow International *Hemosonic 100 Cardiac Output Monitor* (originally approved as the Sometec, Inc. DYNEMO 3000) – 510(k) No. K972798

Appendix 2A

(4) Device Description and Intended Use

The *CardioQ* cardiac output and fluid status monitoring system is designed to provide clinicians with real-time information about left-ventricular blood flow. The CardioQ is designed to operate in a clinical setting in which the patients are under general anesthesia or are sedated in the intensive care unit. The CardioQ offers the anesthetist and intensive care physician with beat-to-beat data on cardiovascular status and circulating blood volume, providing immediate feedback on the effect of any therapeutic intervention.

The CardioQ system employs esophageal Doppler using 4 MHz continuous wave ultrasound to monitor and quantify the blood flow in the descending thoracic aorta, displaying this data as a maximum velocity curve, a velocity spectrum and derived measurements. Thus, real-time information about cardiac function and haemodynamic status, in particular left ventricular flow, is displayed continuously.

The CardioQ system transmits the 4 MHz ultrasonic 'carrier' signal from the probe tip at a fixed angle to the descending aorta, by excitation of a piezo-electric transducer. The ultrasound is reflected by the red blood cells and is received by a separate transducer in the probe tip. Blood flow away from the probe results in frequencies less than 4 MHz being present in the received signal. Conversely, any reverse flow will produce frequencies higher than the carrier.

The received signal is first demodulated, such that those frequencies corresponding to the blood flow are extracted and displayed as a real-time velocity spectrum. The spectrum displays the *distribution* of red blood cell velocities at a given point in time, i.e. a histogram of velocities over time. Thus, the brightness at any point in the spectrum is directly proportional to the number of red blood cells traveling at a given velocity at a given time in the cardiac cycle.

The CardioQ automatically traces the maximum velocity of the spectrum at each time point. By calculating the area under this maximum-velocity curve during systole, a beat-to-beat value for Stroke Distance (SD) is given, being the distance a column of blood moves in the aorta during systole. Using a proprietary algorithm called the nomogram, the CardioQ estimates Stroke Volume (SV) using the measured SD and the size and age of the patient. The Stroke Volume is the volume of blood output by the left side of the heart during systole. Since the machine automatically calculates the patient's heart rate (HR) from the spectrum, it can also provide a beat-to-beat measurement of Cardiac Output (SV*HR). Other parameters calculated include:

- Peak Velocity (PV) - *highest blood velocity recorded during systole*
- Mean Acceleration (MA) – *acceleration of the blood at the beginning of systole*
- Corrected Flow Time (FTc) – *systolic flow time (normalized to 60 bpm)*

- Cardiac Index (CI) – *cardiac output normalized to body surface area*
- Minute Distance (MD) – *a linear surrogate for cardiac output, being the distance a column of blood moves in the aorta in one minute*

The *CardioQ* Cardiac Output and Fluid Status Monitoring System is comprised of the following components:

CardioQ monitor

Esophageal Doppler monitor (including power cord) which generates and processes the transmitted and received ultrasound signals, displays the resulting velocity spectrum and calculates the associated cardiac parameters. It is connected to the probe via the patient interface cable. The monitor displays the waveform and numerical data on a 10.4" color TFT LCD screen, which also provides the user interface and 'help' text. The monitor is operated by a large rotary 'encoder' knob and six 'soft' buttons whose function depends on the current screen mode. The monitor operates from a 100 – 240V A.C. supply.

Patient Interface Cable

6' 3" long interconnect cable between the CardioQ monitor and probe, providing signal amplification and electrical isolation.

CardioQ probe

Esophageal Doppler monitor probe is placed orally and inserted to a depth of 35 – 40 cm, (approx. 14" – 16") for insonation of the descending thoracic aorta at the 6th thoracic vertebra (approximately). The CardioQ probe is the only component in contact with the patient and is manufactured with an outer insulating cover of medical grade silicone rubber. The probe is flexible and has a shaft diameter of 17 French (~5.5 mm, approx. 0.22"). The probe is supplied sterile and is for single-use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2003

Mr. Lawrence Brookfield
Quality Assurance & Regulatory Affaires Manager
Deltex Medical
Terminus Road
Chichester, West Sussex
United Kingdom PO19 8TX

Re: K031706
CardioQ™ cardiac output and fluid status monitoring system
Dated: May 29, 2003
Received: June 2, 2003
Regulatory Class: II
21 CFR 870.2100/Procode: 74 DPW
21 CFR 870. 2120/Procode: 74 DPT
21 CFR 870.2900/Procode: 74 DSA

Dear Mr. Brookfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CardioQ™ cardiac output and fluid status monitoring system, as described in your premarket notification:

Transducer Model Number

CardioQ Probe 9650-7001

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-

4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Frank Lacy at (301) 443-8517, ext. 157.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K03170

Appendix 3C

510(k) number (if known): Page 1 of 1

Unknown - not yet assigned by FDA.

Device name:

CardioQ™ *cardiac output and fluid status monitoring system*

Indications for use of the device:

The *CardioQ* cardiac output and fluid status monitoring system is designed to provide clinicians with real-time information about left-ventricular blood flow. The CardioQ is designed to operate in a clinical setting in which the patients are under general anesthesia or are sedated in the intensive care unit. The CardioQ offers the anesthetist and intensive care physician with beat-to-beat data on cardiovascular status and circulating blood volume, providing immediate feedback on the effect of any therapeutic intervention.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031706

(Optional format 1-2-96)

K031706

CARDIOQ (SYSTEM) Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal					N					
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: THE CARDIOQ MONITORS CARDIAC FUNCTION BY MEASURING BLOOD FLOW IN THE DESCENDING AORTA WITH A TRANSESOPHAGEAL CWD PROBE.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

F-3 **510(k) Number** K031706

Appendix 3A